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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/671,283 | 09/27/2000 | John A. Giordano | 22920.0003 | 6590 |
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PRESTON GATES ELLIS & ROUVELAS MEEDS LLP
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WASHINGTON, DC 20006

EXAMINER

WANG, SHENGJUN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 08/13/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/671,283

Applicant(s)

GIORDANO ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,14-20,22-30,36-38,41 and 117-136 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,14-20,22-30,36-38,41 and 117-136 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.

- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)

- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

- 5) ☐ Notice of Informal Patent Application (PTO-152)

- 6) ☐ Other:

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted May 23, 2003 is acknowledged.

Claim Rejections 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 14-15, 18-20, 22-30, ~~36~~ 38, 41, 117-120, 122 and 124-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128) for reasons set forth in the prior office action.

3. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of McLeod (US 5,898,036) for reasons set forth in the prior office action.

4. Claim 121 is rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of Anderson (US 5,278,329) for reasons set forth in the prior office action.

Response to the Arguments

Applicants' amendments and remarks submitted May 23, 2003 have been fully considered, but are not persuasive for reasons discussed below.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a

sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As disclosed by the cited references, the claimed ranges of each and every well-known nutrients are within the ranges disclosed by the references. As stated in the prior office action: "optimization of the amounts of active ingredients in a nutrient or therapeutical composition is within the skill of the artisan, especially within a known range. such optimization is considered to be an optimization of a result effective parameter, which is considered within the skill of the artisan. See, *In re Boesch and Slaney* (CCPA) 204 USPQ 215." As to the optimization within the range disclosed by references, applicants' attention is further directed to MPEP 2144.05. It is well settled that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In *re* Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In *re* Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); In *re* Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997).

5. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.

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1992). In this case, the teaching, suggestion and motivation are found both in the cited references and the knowledge generally available to one of ordinary skill in the art. Particularly, Reliy teaches the nutritional composition comprising up to 800 mcg of folic acid. Wakat teaches that folic acid, as nutritional supplements may be in the range of 300 mcg to 10 mg. Therefore, it would have been prima facie obvious to employ more than 800 mcg of folic acid in Reliy's nutritional composition. The motivation to combine is based on the facts that folic acid are known to be useful with all the other well-known nutrients herein listed, and are known to be in various combination with other well-known nutrients in the amount up to 10 mg. With respect to the rejection of claims 16 and 17, Mcleod and Anderson teaches the particular chromium or zinc compounds herein employed are known to be used as chromium or zinc supplements. The employment of the particular salt is obvious as stated in the prior office action.

6. In response to applicants' remarks on In re Boesch and Slaney, note, second reference has been cited to address the limitation of "at least 800 mcg folic acid." Further, "about 800 mcg" is overlap with "at least 800 mcg."

Nothing unobvious is seen in the claimed invention.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

A handwritten signature in black ink, appearing to read 'Shengjun Wang', is written over a faint, rectangular stamp that contains the words 'PATENT EXAMINER'.

Shengjun Wang

August 4, 2003